

Dakai Liu and Elazar Rabbani
Serial No. 09/046,840
Filed: March 24, 1998
Page 3 [Amendment Under 37 C.F.R. § 1.115 (In Response To The March 18, 1999 Office Action)- February 14, 2000]

REMARKS

Reconsideration of this application is respectfully requested.

Claims 68-84 were previously pending. Claim 78 has been amended. No other claims have been amended, added or canceled. Accordingly, claims 68-84 as amended hereinabove are presented for further examination on the merits.

In a sincere effort to define their invention more clearly, Applicants have amended claim 78 above. As now amended, this claim recites "[t]he packaging cell line of claim 77, wherein said cell line is native to said first viral vector, said second viral vector, or both." It is believed that the language in claim 78 addresses the issue of claim clarity as set forth in the March 18, 1999 Office Action (page 6).

Before turning to the issues at hand, Applicants and their attorney acknowledge with appreciation the indication from the Examiner that the Sequence Listing from the parent application will be used to prepare a file for the present application.

The Rejection Under 35 U.S.C. § 102(e)

Claims 68-79 and 81-84 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Wong-Staal et al. (U.S. Patent No. 5,650,309). In the Office Action (pages 2-3, the Examiner stated:

This rejection is maintained for reasons of record in the previous Office Action (Paper #4) and for reasons outlined below.

Applicants traverse this rejection by asserting that the Wong-Staal et al. reference does not disclose nucleic acid constructs wherein the second viral nucleic acid or the second nucleic acid construct is structurally different from the first (I) viral nucleic acid or the first (ii) nucleic acid construct, or more than one packaging component for the second viral vector is different from said first viral vector packaging component or components (b), or both.

Applicants' arguments filed 12/18/98 have been considered but are not deemed persuasive. As noted in the previous Office Action, Wong-Staal et al. recites the generation of a recombinant vector (a first vector) comprising sequences from retrovirus and AAV genomes, wherein said first vector can produce a second vector which can be

Dakai Liu and Elazar Rabbani
Serial No. 09/046,840
Filed: March 24, 1998
Page 4 [Amendment Under 37 C.F.R. §1.115 (In Response To The March 18, 1999
Office Action)- February 14, 2000]

single or double stranded RNA or DNA and hence is structurally different from the first vector. With regard to the differences in packaging components, it is noted that packaging components comprising different surface or envelope components provided in the packaging cell can package the AAV portion of a chimeric AAV/HIV vector into AAV particles which have more than one packaging component different from the original HIV particle. Therefore, it must be assumed that Wong-Staal et al. teaches the invention as claimed.

The anticipation rejection is respectfully traversed.

For reasons already of record, Applicants maintain that the instant claims are patentably novel from Wong-Staal et al.'s cited disclosure.

Reconsideration and withdrawal of the anticipation rejection is respectfully requested.

The Rejection Under 35 U.S.C. §102(b)

Claims 68 and 70-74 stand rejected under 35 U.S.C. §102(b) for being allegedly anticipated by Salmons et al. "Targeting of Retroviral Vectors for Gene Therapy," Human Gene Therapy 4:129-141(1993). In the Office Action (pages 3-4), the Examiner stated:

Applicants' traverse of this rejection is similar to the traverse of the above 35 USC 102(e) rejection of claims 68-79 and 81-84.

Salmons et al. teaches the claimed invention because the reference teaches a first and second vector wherein the two vectors differ in chemical structure (i.e. a DNA provirus vector vs. an RNA viral vector) wherein the second vector is capable of expressing an exogenous gene in a target cells and said vector contains a promoter, enhancer, termination sequences, etc. Therefore, Salmons et al. anticipates the claimed invention.

The anticipation rejection is respectfully traversed.

It is believed that Salmons et al.'s review article does not anticipate the instant invention for reasons already stated of record. Withdrawal of the anticipation rejection is respectfully requested.

Dakai Liu and Elazar Rabbani
Serial No. 09/046,840
Filed: March 24, 1998

Page 5 [Amendment Under 37 C.F.R. §1.115 (In Response To The March 18, 1999 Office Action)- February 14, 2000]

Commonality of Ownership

Applicants affirm that the subject matter of the various claims in this application was commonly owned at the time any inventions covered therein were made.

The Rejection Under 35 U.S.C. §103(a)

Claim 80 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wong-Staal et al. (U.S. Patent No. 5,650,309) in view of Bank et al. (U.S. Patent No. 5,278,056). On pages 4-5 of the Office Action the Examiner stated:

Applicants claim a packaging cell line (such as NIH 3T3) for propagating the vector of claim 68, wherein the first vector comprises a retrovirus and wherein the second vector comprises an adeno-associated virus.

Wong-Staal et al. is applied as in the above 35 USC 102(e) rejection of claims 68-79 and 81-84. Wong-Staal et al. does not recite the claimed packaging cell lines.

Bank et al. recites the use of the NIH 3T3 cell line as a packaging cell line for retroviral vectors.

The claimed subject matter is disclosed by Wong-Staal et al. with the exception of using the recited packaging cell lines recited in claim 80. The ordinary skilled artisan would have been motivated to use a well known packaging cell line (such as NIH 3T3) to package the claimed vectors since Bank et al.; teaches use of the NIH 3T3 cell line for packaging retroviral vectors. It would have been obvious for the ordinary skilled artisan to use a cell line such as NIH 3T3 because Bank et al. indicates that this cell line can be used to package retroviral vectors. Indeed, applicants themselves admit that the packaging cell line for the claimed vectors can be selected from a variety of packaging cell lines which are known in the art (See Specification, p. 28). Given the well known teachings of the cited references and the level of skill in the art at the time the invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The obviousness rejection is respectfully traversed.

Dakai Liu and Elazar Rabbani
Serial No. 09/046,840
Filed: March 24, 1998
Page 6 [Amendment Under 37 C.F.R. §1.115 (In Response To The March 18, 1999
Office Action)- February 14, 2000]

Applicants reiterate their previous response that the differences between the present invention at hand and the combined cited disclosures would not have been obvious to a person of ordinary skill in the art at the time their invention was made.

Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

The Rejection Under 35 U.S.C. §112, Second Paragraph

Claim 78 stands rejected for alleged indefiniteness for failing to point out and distinctly claim the subject matter which applicant regards as the invention. In the Office Action (page 6), the Examiner stated that:

The rejection of claim 78 is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection the term "native" is sufficiently clear when read in light of the specification.

Applicants' arguments have been considered but are not persuasive. While applicants' explanation of the meaning of the term "native" with relation to the cell line for the viral vector is agreed with, it is again noted that the claimed viral vectors can comprise portions of two or more viruses, each with its own "native" cell line. Therefore, it is unclear what "native" cell is being referred to in the claim.

The indefiniteness rejection is respectfully traversed.

As indicated in the opening remarks of this paper, claim 78 has been amended above in a sincere effort to improve the clarity of its claim language. The new language in this claim is directed to "[t]he packaging cell line of claim 77, wherein said cell line is native to said first viral vector, said second viral vector, or both." Claim 77 is dependent from claim 75, the latter reciting "[t]he first vector of claim 68, wherein said first vector comprises a retrovirus and said second vector comprises adeno-associated virus." Thus, the language in claim 78 properly refers to the cell line as being native to the first viral vector, the second viral vector, or both. It is believed that the foregoing amendments to claim 78 address the issue under 35 U.S.C. §112, second paragraph, by meeting the Examiner's requirements or adopting his inferred suggestions for claim definiteness.

Dakai Liu and Elazar Rabbani
Serial No. 09/046,840
Filed: March 24, 1998
Page 8 [Amendment Under 37 C.F.R. § 1.115 (In Response To The March 18, 1999
Office Action)- February 14, 2000]

SUMMARY AND CONCLUSIONS

Claims 68-84 are presented for further examination, claim 78 having been amended above.

This Amendment is being accompanied by a Petition Under 37 C.F.R. § 1.137(b) To Revive An Unintentionally Abandoned Application, and authorization for the fee therefor. No other fee is believed due in connection with this filing. In the event that any other fee or fees are due, however, The Patent and Trademark Office is authorized to charge the amount of any such fee(s) to Deposit Account No. 05-1135, and to credit any overpayment thereto.

In view of the above discussion of the issues and amendments to the claims, Applicant respectfully submits that all of the instant claims are in allowable condition. Should it be deemed helpful or necessary, the Examiner is respectfully invited to telephone the undersigned at (212) 583-0100 to discuss the subject application.

Respectfully submitted,


Ronald C. Fedus
Registration No. 32,567
Attorney for Applicant

ENZO THERAPEUTICS, INC.
c/o Enzo Biochem, inc.
527 Madison Avenue, 9th Floor
New York, New York 10017
Tel.: (212) 583-0100
Fax.: (212) 583-0150

L:\lenz56(D3)\amendment\Enz56(d3).021400

SEQUENCE LISTING

<110> Liu, Dakai
Rabbani, Elazar

<120> VECTORS AND VIRAL VECTORS, AND PACKAGING CELL LINES FOR
PROPOGATING SAME

<130> ENZ-56SequenceListing.110398

<140> 08/822,963
<141> 1997-03-21

<160> 16

<170> PatentIn Ver. 2.0

<210> 1
<211> 9
<212> DNA
<213> Bacteriophage lambda

<220>
<223> Description of Artificial Sequencenucleic acid,
double stranded, linear topology

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 1
tatcaccgc

9

<210> 2
<211> 9
<212> DNA
<213> bacteriophage 434

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 2
acaagaaaa

9

<210> 3
<211> 10
<212> DNA

<213> Escherichia coli

<220>

<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 3
gtactagttta 10

<210> 4
<211> 8
<212> DNA
<213> Escherichia coli

<220>

<223> Description of Artificial Sequence:nucleic acid,
double stranded; linear topology

<400> 4
agacgtctt 8

<210> 5
<211> 24
<212> DNA
<213> Escherichia coli

<220>

<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 5
tggaatttgtg agcgataaac aattt 24

<210> 6
<211> 4
<212> DNA
<213> Drosophila melanogaster

<220>

<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 6
taat 4

<210> 7
<211> 9
<212> DNA

<213> MAT alpha 2 yeast
<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 7
catgttaatt

9

<210> 8
<211> 13
<212> DNA
<213> Escherichia coli

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 8
aaaagtgtga cat

13

<210> 9
<211> 11
<212> DNA
<213> GAL4 yeast

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 9
ccggaggaca g

11

<210> 10
<211> 12
<212> DNA
<213> Papillomavirus sylvilagi

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 10
accgacgtcg gt

12

<210> 11
<211> 6
<212> DNA

<213> GCN4 yeast
<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 11
atgatc

6

<210> 12
<211> 9
<212> DNA
<213> zif268 murine

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 12
gcgtggcg

9

<210> 13
<211> 9
<212> DNA
<213> human glucocorticoid

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 13
cagaacatc

9

<210> 14
<211> 8
<212> DNA
<213> tfiid

<220>
<223> Description of Artificial Sequence:nucleic acid,
double stranded, linear topology

<400> 14
tatataaa

8

<210> 15
<211> 319
<212> DNA

<213> murine leukemia virus

<220>

<223> Description of Artificial Sequence:nucleic acid,
single stranded, linear topology

<400> 15

gaacagatgg aacagctgaa tatggccaa acaggatatc tgtggtaagc agttcctgcc 60
ccggctcagg gccaaagaaca gatggAACAG ctgaatatgg gccaaACAGG atatctgtgg 120
taagcagttc ctgccccggc tcagggccaa gaacagatgg tccccagatg cggtccagcc 180
ctcagcagtt tctagagaac catcagatgt ttccagggtg ccccaaggac ctgaaatgac 240
cctgtgcctt atttgaacta accaatcaagt tcgcttctcg cttctgttcg cgcgcttctg 300
ctccccgagc tcaataaaa 319

<210> 16

<211> 319

<212> DNA

<213> murine leukemia virus

<220>

<223> Description of Artificial Sequence:nucleic acid,
single stranded, linear topology

<400> 16

acgcttgatc cggttacactg cccattcgac caccaAGCgA aacatcgcat cgagcgagca 60
cgtaCTCGA tggaAGCCGG tcttgtcgat caggatgatc tggacgaaAGA gcatcaggGG 120
ctcgccggcag ccgaACTGTT CGCCAGGCTC aaggcgCGCA tgcccacgg cgaggatctc 180
gtcgtgactt tctagagaac catcagatgt ttccagggtg ccccaaggac ctgaaatgac 240
cctgtgcctt atttgaacta accggtcagt tcgcttctcg cttctgttcg cgcgcttctg 300
ctccccgagc tcagctgcg 319